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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,776	04/27/2001	Christian Reiter	41735	4137

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/03/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/842,776

Applicant(s)

Reiter et al

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 13, and 14 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 13, and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, claims 1-4 and 13-14 in Paper No. 15, received May 1, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

2. Claims 1-4 and 13-14 are objected to because of the following informalities: Claims 1-4 and 13-14 recite non elected aptamers. Appropriate correction is required.

SEQUENCE LISTING

3. Applicants attention is drawn to the entire specification and Figures which contain numerous sequences without appropriate SEQ ID NO tags. To fully comply with the sequence requirements applicant is required to give a sequence identification tag to all amino acid sequences of at least 4 amino acids or 10 nucleotides or longer. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

4. Claims 1-4, and 13-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to methods for detecting an infection of an acid-resistant microorganism in stool with a monoclonal antibody or “fragment or derivative thereof.”

CDR's are hypervariable regions of a monoclonal antibody, which impart the antibody its given affinity, specificity, and avidity for a particular immunogen. For a given antibody there will be 6 CDR's each with a defined amino acid sequence, any antibody which does not contain these CDRs in their proper orientation will not necessarily translate into a functioning antibody.

Furthermore, Applicants claim encompasses sequences as small as a single amino acid (fragment), one of skill in the art would not expect a single amino acid to retain antigen binding activity.

Finally, Applicants recitation of “derivative” allows for multiple amino acid substitutions, deletions and insertions, however, retaining affinity while freely substituting amino acids is simply unpredictable. Rudinger et al “Peptide Hormones” edited by Parsons et al, University Park Press, June 1976, pages 1-7, especially page 6 teach that “the significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted a priori but must be determined from case to case by painstaking experimental study.” In view of the lack of guidance,

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lack of examples, and lack of predictability associated with regard to producing and using the myriad of derivatives encompassed in the scope of the claims one skilled in the art would be forced into undue experimentation in order to practice broadly the claimed invention.

5. Claims 1-4 and 13-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to methods for detecting an infection of an acid resistant microorganism in the stool wherein the monoclonal antibody binds an "epitope of the first antigen" and "an epitope of a second antigen" and binds β urease "fragments" or 26 kDa "fragments" or Hsp60 "fragments."

Fox (U.S. Patent Number 4,879,213) sets forth that "without knowing a protein's three dimensional structure there is no reliable method for determining which linear segments of the protein are accessible to the host's immune system" and that "whether the three dimensional structure is known or not, short linear polypeptides often appear not to have the ability to mimic the required secondary and tertiary conformational structures to constitute appropriate immunogenic and antigenic determinants." (See column 3) Consequently one of skill in the art would be forced into excessive experimentation to identify which "fragments" are able to mimic

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the required secondary and tertiary structure of the full length polypeptide, and which fragments are capable of complexing with the monoclonal antibody that recognizes the full length polypeptide.

6. Claims 1-4, and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the use of the phrase "derivative." Since it is unclear if the monoclonal antibody or fragment are undergoing any kind of chemical modification as implied by the recitation of "derivative." Since it is unclear how the monoclonal antibodies or fragments are to be derived as referred to in the claims, there is no way for the person of skill in the art to ascribe a discrete and identifiable definition to said phrase.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Larka et al.

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The claims are directed to a method for detecting an infection of an acid-resistant microorganism wherein a stool sample of a mammal is incubated with at least two different monoclonal antibodies, wherein the first monoclonal specifically binds an epitope of the first antigen, and the second monoclonal binds an epitope of a second antigen and detecting the formation of the antigen-antibody complex.

Larka et al (US Patent Number 5,932,430) disclose of a process for the determination of H. pylori in a fecal specimen comprising contacting the fecal specimen with a plurality of antibodies and detecting the antigen-antibody complex. (See claim 1).

Larka et al further define "plurality of antibodies" as a polyclonal antibody and a mixture of monoclonal antibodies." (See column 2).

Consequently, the disclosure of Larka et al of a mixture of monoclonal antibodies to detect H. pylori in a stool sample is deemed to anticipate the instantly claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

June 26, 2003